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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,151	01/11/2002	Graham Stephen Le Gros	P65506US0	3691

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,151	LE GROS ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35 - 62* is/are pending in the application.

4a) Of the above claim(s) *50-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 35 - 62 are pending.

2. Applicant's election without traverse of Group I, claims 35-49 in Response to restiction Requirement, filed on 04/06/04 is acknowledged.

Claims 50-62 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 35-49 are under consideration in the instant application.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it was not executed in accordance with either 37 CFR 1.66 or 1.68. There are 5 inventors of the instant Application, however, said declaration was signed only by 4 inventors.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. In claim 41 it is apparent that *M. bovis*, starin AN5 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of *M. bovis*, starin AN5 . See 37 CFR 1.801-1.809.

If the deposit have been made under the terms of the Budapest treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the *M. bovis*, starin AN5 has been deposited under the Budapest Treaty and that the said strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or for the enforceable life of the patent whichever is longer. See 37 CFR 1.806 1.808 (a)(2) and MPEP 2410-2410.01.

If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in position to make such assurances, or statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met

Amendment of the specification to disclose the date of the deposit and complete name and address of the depository is required

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

8. Claims 35 - 49 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,238,676.

US Patent '676 teaches a vaccine comprises as an active agent an immunogenic lipoarabinomannan (LAM) an adjuvant and a pharmaceutically acceptable carrier. (see entire document, Claim 1 in particular). US Patent '676 teaches LAM can be isolated from *Mycobacterium bovis* (see claim 3 and column 20 in particular) and further teaches a method of isolating LAM from *Mycobacterium bovis* that is the same as was used in the instant application (see examples 8 and 9 in particular). US Patent '676 teaches a vaccine which further comprises a secondary immunogen which are Th1 type immune response inducing substances (see claim 13 in particular).

Claims 37 is included because the claimed functional limitation would be inherent properties of the referenced vaccine. A vaccine comprising as active agent LAM taught by US Patent '676 is the same as claimed irrespective of what its intended use. The term "formulated for respiratory administration" carries little patentable weight in the absence of evidence of structural difference. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. vaccine comprising LAM) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

Claim 41 is included because the claimed functional limitation would be inherent properties of the referenced vaccine. It is noted that the referenced vaccine composes as active agent LAM that was obtained from *Mycobacterium bovis* i.e. the same LAM that is isolated from *Mycobacterium bovis* strain AN5 in the absence of evidence of structural and functional difference. Since the office does not have a laboratory to test the reference vaccine, it is applicant's burden to show that the reference LAM, isolated from *Mycobacterium bovis* is not the same LAM isolated from *Mycobacterium bovis* strain AN5 as claimed. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 42 – 45 are included because the claimed functional limitation would be inherent properties of the referenced vaccine. It is noted that the referenced vaccine composes as active agent LAM that was obtained from *Mycobacterium bovis* by the same way as disclosed in the instant specification thus it would inherently be free of bacterial nucleic acid and contains saccharide component as claimed. Since the office does not have a laboratory to test the reference vaccine, it is applicant's burden to show that the reference LAM does not free of bacterial nucleic acid and contains saccharide component as claimed. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teaching anticipates the claimed invention.

11. Claims 35- 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,569,436 in view of Stankovic et al (IDS).

US Patent '463 teaches a vaccine for inducing an immune response in a patient effective to treat asthma which comprises as an active agent *Mycobacterium bovis* (see entire document, Abstract and claims in particular). US Patent '463 teaches that said vaccine should be formulated for administration to the respiratory tract (see claim 2 in particular). US Patent '463 teaches that said vaccine comprises mainly cell wall component of *Mycobacterium bovis* (see column 3 in particular).

US Patent '463 does not explicitly teach a vaccine which comprises lipoarabinomannan (LAM) isolated from *Mycobacterium bovis.*

Stankovic et al., teach that LAM is a major component of the cell wall of *Mycobacterium bovis* (see page 37 in particular). Stankovic et al., teach a method of isolating LAM from *Mycobacterium bovis* and further teach that LAM shown to be better than *Mycobacterium bovis* as eosinophilia suppressor in the lung and thus can be used in vaccine to treat asthma (see page 38 in pareticular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Stankovic et al., to those of US Patent '436 to obtain a claimed vaccine which comprises lipoarabinomannan (LAM) isolated from *Mycobacterium bovis.*

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because LAM is a major component of the cell wall of *Mycobacterium bovis* and shown to be better than *Mycobacterium bovis* as eosinophilia suppressor in the lung and thus can be used in vaccine to treat asthma as taught by Stankovic et al. Said LAM can substitute *Mycobacterium bovis* or be added in addition, as a secondary immunogen in the vaccine taught by US Patent '463 . "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06). The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

Claim 41 is included because a person of ordinary skill in the art at the time the invention was made would expect that LAM that has been isolated form *Mycobacterium bovis* starain AN5 would have the same structure and function as LAM that has been isolated form *Mycobacterium bovis* as taught by Stankovic et al., absent a showing of unobvious property.

Claims 42 – 45 are included because the claimed functional limitation would be an obvious properties of the referenced vaccine. It is noted that the Stankovic et al., teaches LAM that was obtained from *Mycobacterium bovis* by the same way as disclosed in the instant specification thus it would obviously contains saccharide component as claimed.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. No claim is allowed.

13. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
May 17, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600